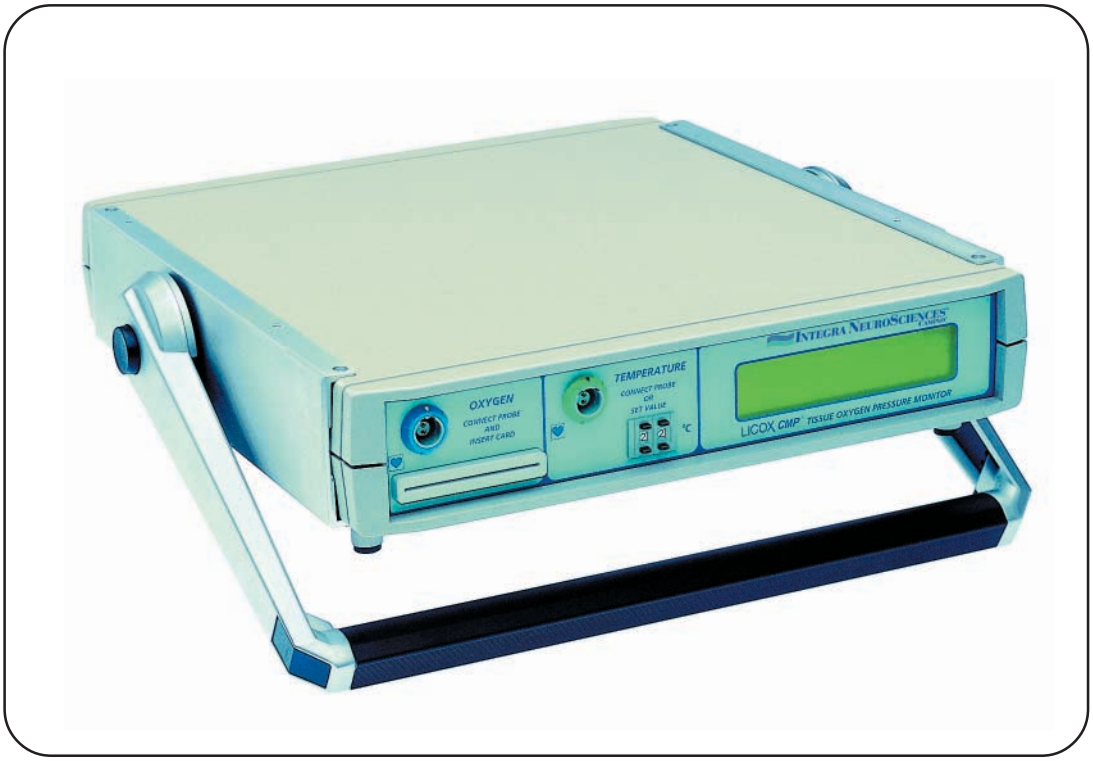
LICOX® CMP

Brain Oxygen Monitoring System
Operations Manual



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1 Introduction

The LICOX CMP instrument is used for continuous determination of *oxygen partial pressure ($p_{bt}O_2$)* in cerebral spinal fluid and brain tissue. Minimally invasive catheter microprobes are implanted directly into brain tissue and are connected to the CMP monitor via an electrical cable. *Tissue temperature* can also be continuously measured and used for temperature compensation of $p_{bt}O_2$ measurements, if a separate temperature sensing catheter is used.

In clinical use however, the LICOX CMP instrument can not be used for blood gas monitoring.

The catheter employs an electrochemical (polarographic) micro-cell for oxygen sensing. The temperature catheter employs a (type K) *thermocouple*.

Due to its smart card technology, minimal time and effort is required to calibrate the system before use. Calibration data is stored on a smart card supplied with each catheter. When the smart card is inserted into the LICOX CMP instrument, the system calibrates automatically and is ready for use. Oxygen catheters may be disconnected during use and re-connected to any CMP monitor, as long as the catheter and it's smart card are connected to the same CMP monitor. A catheter implanted in the ER can be reconnected to a second CMP unit located in the ICU or elsewhere.

The LICOX CMP data can be displayed in the following ways:

- The LICOX CMP instrument can be used as a simple stand alone monitor with digital display of the $p_{bt}O_2$ values.
- The oxygen pressure and temperature data measured by the LICOX system may also be sent to patient monitors, e.g. Hewlett Packard, Marquette, etc., for display, storage and processing. This is accomplished by the use of the LICOX LML interface device and cables.

2 Indications for Use

The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

3 Important Notes

Device Classifications and Standards

This instrument has been designed for constant use.

Electrical safety meets EN 60601-1 (including amendments 1 and 2), Type CF.

Immunity from electromagnetic disturbance meets IEC 801 including ext. No. 2, 3, 4, 5.

Maximum electromagnetic emission meets EN 55011, Group 1, Class B.

Warning Instructions

Failure to observe one or more of the following warnings could compromise the safety of the patient or result in measurement errors. This also applies to warnings that are issued at other locations throughout this operation manual; sections in which reference is made to dangers or to possible operating errors are marked in this document with an index-finger symbol " ☞ ":

☞ a The LICOX CMP instrument may only be used per the “Indications for Use” section of this document.

☞ b The LICOX CMP instrument may only be used when device mainte nance has been carried out.

☞ c The use of excessive force on the instrument may seriously damage it; the same applies to the cable and to the sensor. All mechanical fea tures of the LICOX system can be operated without the use of exces sive force.

☞ d The housing of the unit and/or the wall power supply must not be opened. Units must be returned to the manufacturer for repair and service.

☞ e Only original LICOX parts may be used with or on the instrument. This applies in particular to all $p_{bt}O_2$ probes, probe cables, analog transmission cables and the power supply.

☞ f The instrument, the power supply and the cable connectors must be protected against moisture and wetness.

☞ g The instrument must be switched off before cables are connected or disconnected at the rear of the device.

☞ h Probe cables (or extension probe cables) with damaged isolation jacketing must not be used. Connector contacts must be cleaned after coming into contact with saline solutions or body fluid. Measurement error can occur if these recommendations are not observed.

☞ i Probe extension cables may not be used when their connectors are wet or damp. Measurement errors can occur if this recommendation is not observed.

☞ j The potential equalisation plug at the rear of the device must be connected to the hospital grounding system, when available.

☞ k The anesthetic gas halothene disturbs measurement with all types of polarographic $p_{bt}O_2$ probes. After an initial exposure time of 5 to 20 min., the displayed $p_{bt}O_2$ value is overestimated; this effect is usually reversible. However, other common anesthetic gases such as nitrous oxide (N_2O), enflurane and isoflurane can be used without impairing the accuracy of the measurement.

☞ l Strong electrical interference (e.g. during cauterization) can cause a disturbance of the measurement that outlasts the interference by a few seconds.

☞ m The device has not been designed for use in areas where there is a risk of explosion.

☞ n Only use the prescribed cleaning agents and methods when cleaning and disinfecting the instrument and the cable.

☞ o Disposable probes and accessories are for single use only.

☞ p In hyperbaric medicine, the instrument may be used in an air-filled (not enriched with O_2!) pressure chamber up to a pressure of 3 bar. The power supply (low voltage DC) is connected through the wall of the chamber from the outside using suitable connectors. On precisely speci fied demand, a custom-made cable can be obtained from the manufac turer, or the manufacturer of the pressure chamber. This authorization to use the LICOX CMP in a pressure chamber does not extend to connected devices. It is, however, generally recommended as a sim pler technical solution for measurement during Hyperbaric Oxygenation (HBO), that the LICOX CMP instrument is set up outside the chamber and that the probe signals be transmitted via bi-polar electrical bush ings. A description of the technical details can be obtained from the manufacturer upon request.

☞ q The measurement error can exceed the defined limits when the cath eter is continuously operated for more than 5 days.

☞ r Facilities for neurosurgical treatment of an intracranial bleed must be available in the hospital.

☞ s Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective UL standards (UL2601 for medical equipment). Furthermore all configurations shall comply with the system standard UL2601. Anyone who connects additional equip ment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the systems standard IEC60601-1. If in doubt consult the technical service department.

☞ t This equipment is not a bloodgas device .

☞ u Disconnect the power supply from outlet to separate from main voltage

4 Oxygen Sampling Method

Relationship between oxygen pressure and oxygen content in biological media

Gases which are in contact with the surface of a liquid become physically dissolved in the liquid. If the pressure, the composition and the temperature of the gas atmosphere over the liquid remain constant over time, a stable equilibrium of diffusion is established between the gas and the liquid. Ultimately, the pressure of the gas dissolved in the liquid reaches the pressure of the gas above the liquid. The partial pressure of a gas dissolved

in a liquid is often expressed in units of mmHg, pressure units which correspond to the pressure exerted by a column of mercury of a given height.

As partial pressure increases, the amount of gas that is dissolved in a particular volume of liquid also increases. In other words: the higher the partial pressure of a gas in solution, the higher the concentration.

The $p_{bt}O_2$ value, a measure of cellular oxygen availability

The partial pressure of the oxygen physically dissolved in CSF or brain tissue corresponds to the availability of oxygen at the cellular level, since the cell membranes do not represent a functionally variable O_2 diffusion barrier and because the diffusion distance between the interstitial space and the mitochondria is short. Hence the $p_{bt}O_2$ value reflects the balance between O_2 supply and O_2 demand of the oxidative energy metabolism directly at the target of the complex oxygen transport. An increase in the $p_{bt}O_2$ balance might be due to an increase in the oxygen transport rate to tissue or to a decrease of the tissue oxygen consumption.

Temperature effect

The signal of a polarographic $p_{bt}O_2$ probe (the probe current) changes depending on the temperature, even if the $p_{bt}O_2$ value in the environment remains constant. The change in probe $p_{bt}O_2$ sensitivity with change in temperature is approximately 4% per degrees centigrade. The probes zero signal (current with no oxygen present) does not depend on temperature. The temperature sensitivity of the probe signal is compensated for when the monitor calculates the $p_{bt}O_2$ value. Therefore the temperature of the $p_{bt}O_2$ probe must be supplied to the LICOX CMP instrument. The temperature must be continuously measured by an additional LICOX temperature probe (recommended when the tissue temperature is variable or unknown) or the tissue temperature must be supplied by adjusting a code switch on the front panel of the instrument. The second option may be preferred when the patient‘s core temperature is continuously monitored, for example by the use of a foley catheter with thermistor.

Microtrauma caused by catheter implantation

A local microtrauma results from the implantation of the $p0_2$ probe in the tissue. Tissue is affected in a layer concentrically surrounding the catheter. Several hours after implantation the thickness of that layer is 70 µm to 500 µm.
The $p_{bt}O_2$ value measured corresponds to the mean value of the local $p_{bt}O_2$ levels at the interface between the damaged tissue around the sensor and the surrounding undamaged tissue. Tissue lacking oxidative metabolism is transparent to the $p_{bt}O_2$ measurement. Therefore, the reading is predominantly determined by the $p_{bt}O_2$ in the undamaged tissue.

Immediately after implantation of the $p_{bt}O_2$ catheter, readings are influenced by the developing microtrauma. This applies to the first 10 to 120 minutes after insertion. The $p_{bt}O_2$ values displayed during this initial phase after implantation therefore do not provide relevant information about the oxygenation of the tissue.

5 Operation and Display

Front Panel of the LICOX CMP Monitor

1 Slot for smart card

2 Blue socket for blue cable (REF: BC10PA), cable that connects the $p_{bt}O_2$ probe

3 Code switch for input of patient tissue temperature

4 Green socket for green cable (REF: BC10TA), cable that connects to tissue temperature probe

5 LCD display. Measured data, instructions and error messages

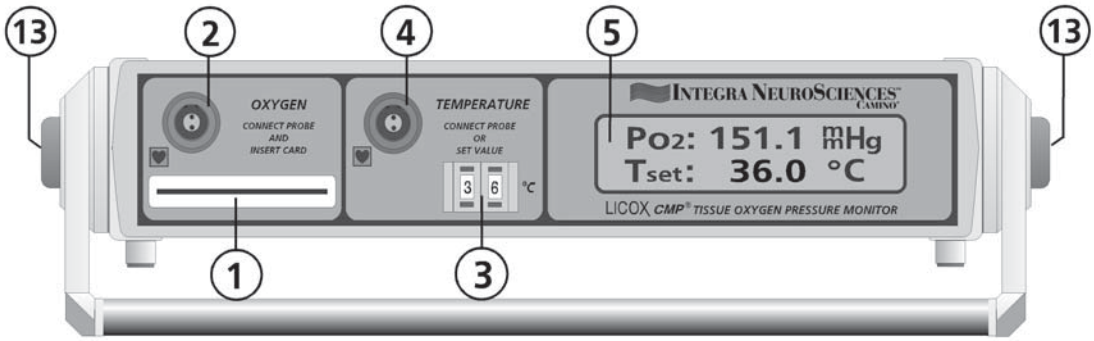

Fig. 1: Front Panel of the LICOX CMP Monitor

Rear Panel of the LICOX CMP Monitor

6 On/Off switch

7 Socket for connection of the LICOX main power supply (6.7 - 7.5 VDC), (REF: A10)

8 Analog $p_{bt}O_2$ signal output (0 to 10 V DC, 10 mV/mmHg)

9 Analog temperature signal output (0 to 10 V DC, 100 mV/°C)

10 *LICOX bus* socket
The analog signal output (No. 8 of Fig. 2) and bus socket (No. 10 of Fig. 2) may be connected (by using the cable REF D11) to the LICOX monitor Link A for $p_{bt}O_2$ signal transfer to a bedside monitor. (See Directions for Use, REF: LML.1.)

11 Fuse (500 mA, slow-acting)

12 Potential equalisation plug

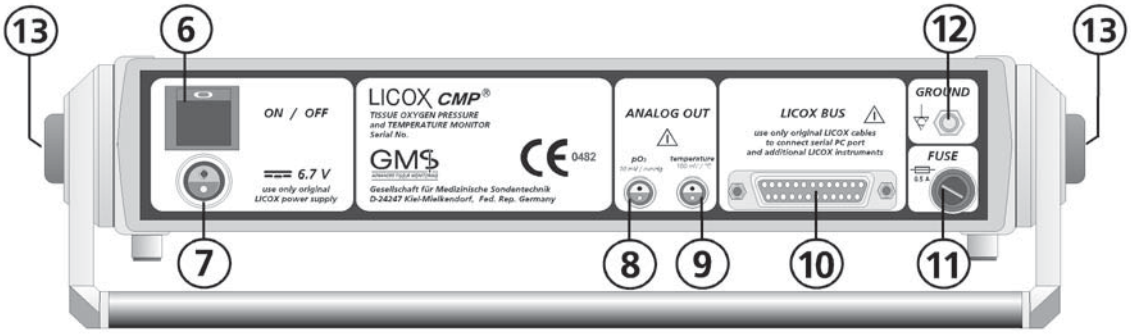

Fig. 2: Rear Panel of the LICOX CMP Monitor

Handle of the LICOX CMP Monitor

13 By simultaneously pressing firmly on the buttons on both sides of the handle, the handle is unlocked. It can then be rotated to a new position and again locked.

The LCD Display

Identification of parameters

$p_{bt}O_2$ $p_{bt}O_2$ value (0.0 - 1999 mmHg), calculated from the probe current signal and the compensation temperature

T_{SET} patient temperature (28 - 45 °C) set at code switch (No. 3 of Fig. 1)

T_{mp} temperature (0.0 - 46.0°C) measured by the LICOX thermocouple probe connected to the monitor. In tissue, the thermocouple should be near the location of the $p_{bt}O_2$ probe.

Messages on the LCD display

"please insert probe card"

Insert the smart card until it snaps into the chip card slot (No. 1 of Fig. 1). The gold contact pads must point downwards. Push the card in the direction of the arrow labeled on the card until the card snaps into place.

"card orientation wrong -> re-insert"

The smart card has been inserted incorrectly; turn the chip card over and re-insert it.

"please use probe no.: xxx"

Connect the probe with the serial number xxx that corresponds to the smart card connected to the CMP monitor. Or insert the smart card which corresponds to the probe connected to the monitor.

"please connect dummy probe"

This message can only appear when the special smart card used for testing the instrument (REF: BC10R) has been inserted. The message requests that the "dummy probe" be connected to the blue $p_{bt}O_2$ probe cable (REF: BC10PA). The temperature switch must be set to 22°C and any thermocouple-temperature probe must be disconnected.

Error messages on the LCD display

"error no. x service required"

Error numbers 1 to 3 indicate that the instrument is no longer functional and must be returned for repair. A short occurrence of error No. 4 after cardioversion or cauterization or during use of an HF scalpel is normal. The instrument is no longer functional when message no. 4 appears when there is no clearly definable source of the electrical noise- or when the probe cable is removed from the monitor.

"temperature is too low"
The measured temperature is below the lower limit of the operating range, 0°C.

"temperature is too high"
The measured temperature is above the upper limit of the operating range, 46°C.

"temperature is set too low"
The temperature set at the code switch (No. 3) is below the lower limit of the operating range, 28°C.

"temperature is set too high"
The temperature set at the code switch (No. 3) is above the upper limit of the operating range, 45°C.

☞ ***"probe or cable defective"***
The $p_{bt}O_2$ probe pre-amplifier receives a signal that exceeds the probe current operating range. In most of these cases, there is a defect in the $p_{bt}O_2$ probe or in the probe cable. This message, however, also occurs for a short time after connecting a $p_{bt}O_2$ probe which has been previously run, for example when a probe and smart card are transfered from one monitor to another.

The following procedure is used to check whether or not there is a defect in the probe cable: First, the $p_{bt}O_2$ probe should be disconnected from the cable. If the error message is not displayed, the probe is defective. If the error message remains, the probe cable should be disconnected from the instrument. If the error message now disappears, then the probe cable is defective and must be replaced (REF: BC10PA). Note: the contacts may be contaminated. If the error message is displayed even if no cable is connected, then the CMP monitor is in need of repair or cleaning of the input connector may be required.

Explanation of the Symbols on the Front and Rear Panel

Protected against electric shock. Type CF equipment per DIN EN 60601-

potential equalisation point for grounding

Caution: Consult accompanying documents

Instrument meets protection class II

AC voltage

DC voltage

6 Components of the LICOX CMP System

Instruments, Cables and Accessories

Model No.	Description
AC3	LICOX CMP instrument

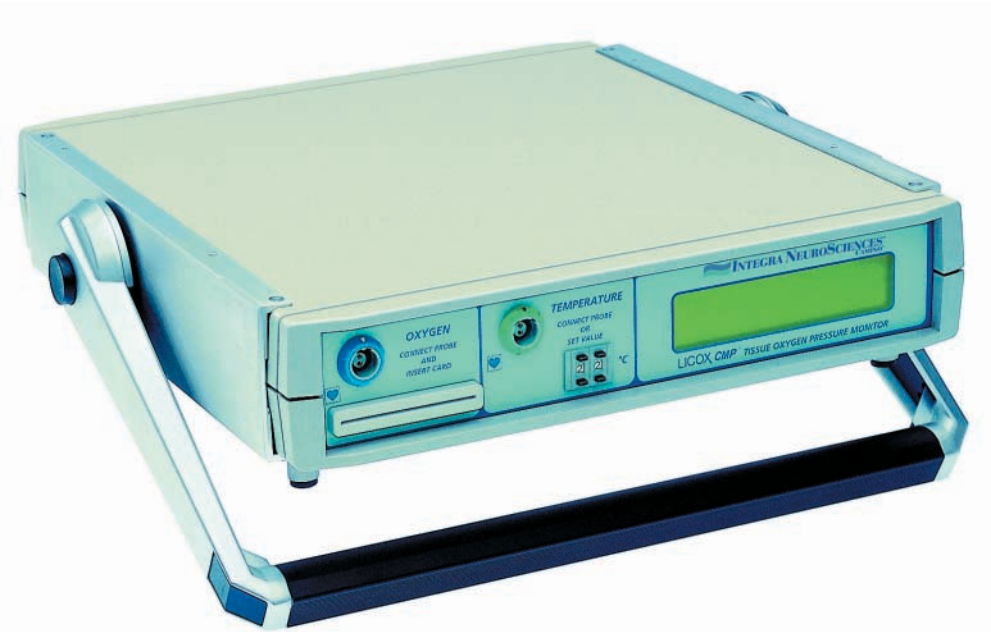

Fig. 3: LICOX CMP Instrument

The following components are delivered with the LICOX CMP instrument (Model No. AC3.1). Please check that all components are included on delivery.

A10	•	LICOX wall connected power supply
BC10PA	•	$p_{bt}O_2$ probe cable (blue), the cable is not suitable for sterilization in autoclave
BC10TA	•	temperature probe cable (green), the cable is not suitable for sterilization in autoclave
BC10PV	•	extension cable for $p_{bt}O_2$ probe (blue) , sterilization in autoclave is possible
BC10TV	•	extension cable for the temperature probe (green), sterilization in autoclave is possible
BC10R	•	test equipment for the functional test of the device: test resistor for input circuit and smart card to activate the diagnostic program
BC10S	•	test plug for the patient saftey test

Optional accessories used in displaying the measured data with other monitoring systems

The LICOX monitor link A, model D1 and connection cables are required to display data obtained with the LICOX CMP instrument on bedside monitors. These cables connect the analog signal outputs of the LICOX CMP with the analog signal inputs of the patient monitoring pressure module. Please refer to Directions for Use (DFU) for model LML.1, D1 for detailed description.

Disposable Catheter Probe and Bolt

☞ The flexible catheter probe is used for monitoring of $p_{bt}O_2$ in tissue and in CSF. The $p_{bt}O_2$ sensor is a closed polarographic cell located at the tip of the completely closed polyethylene (PE) catheter body. The $p_{bt}O_2$ is determined near the tip of the probe in a cylindrical tissue layer located concentrically around the catheter.

There are 2 polarographic electrodes in the polyethylene tube, one made of silver, one of gold; these are connected to the electrical contact pins in the connector housing. The cavity of the PE tube is filled with an electrolyte solution buffered at a pH value of 7.4. **The probe no longer functions if the PE tube is torn or cut.**

Fig. 4 shows a picture of the probe tip. The solid polyethylene tip, the hollow portion of the catheter body which is filled with an electrolyte solution, and the $p_{bt}O_2$ sensitive surface are illustrated.

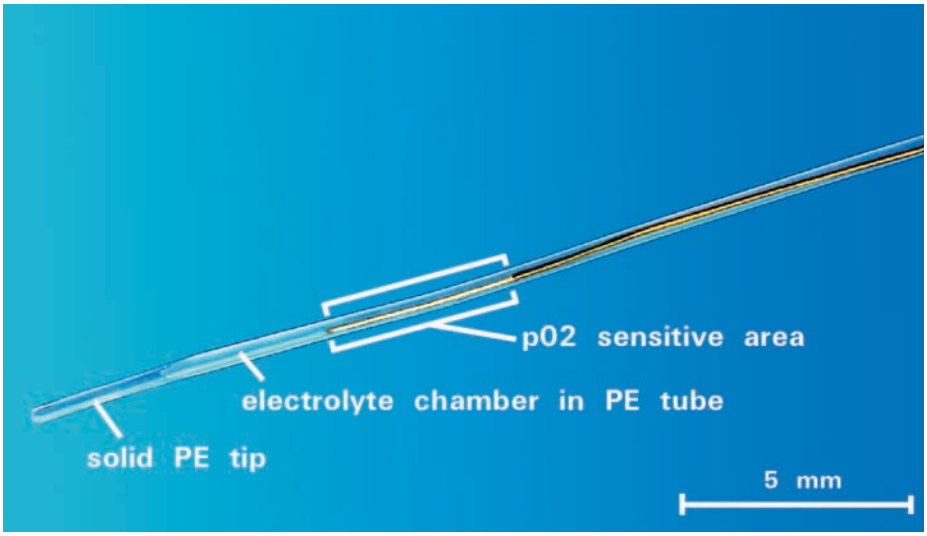

Fig. 4: Tips of oxygen probe Type CC1.SB

Calibration data is determined during manufacture for each probe and is stored on a smart card. The smart card is delivered with the sensor.

The probe is delivered in a waterproof protector tube containing a small volume of an electrolyte solution (phosphate buffer pH 7.4). The protector tube is closed at one end and at the other end is sealed at the probe connector housing by a Luer-type fitting. The probe must be stored in the supplied humid chamber to avoid evaporation of the electrolyte contents. The protector tube must be removed before use.

Store cool, but do not freeze.
Protect from direct sunlight.
Observe the expiration date.
Storage in refrigerator is recommended, but probe should not be frozen.

The probe is double-packed and is delivered sterile.

Disposables

Probe type	Length of the $p_{bt}O_2$ sensitive area (mm)	Distance from tip to sensitive area (mm)	ø catheter near the tip (mm)	ø catheter near the root (mm)	Catheter length (mm)	Cable fix-mounted
CC1.SB	5	5	0.8	<1.0	150	no

Polarographic data

Gold cathode, silver anode

Polarization voltage 795 mV

Stirring artifact < 4%

Zero current < 1 nA

Temperature coefficient of sensitivity ≈ 4%/°C

Probe type	$p_{bt}O_2$ sensitivity at 37 °C ($nA/mmHg\ p_{bt}O_2$)	Response time T_{90} at 35 °C (s)
CC1.SB	≈ 2.8	≈ 290

Model No.	Description
CC1.SB	Probe for intracranial $p_{bt}O_2$ measurement with complete introducer system IMx.xx

Fig. 5: Probe Type CC1.SB with and without protector tube and smart card

Complete system for intracranial $p_{bt}O_2$ measurement

Model No.	Description
IM1.S	Complete bolt kit for intracranial $p_{bt}O_2$ measurement with one access channel; disposable kit with probe CC1.SB, bolt, insertion catheter, drill-bit and accessories

Fig. 6: IM1.S measurement kit completely assembled for intracranial measurement

Multi Channel Bolt Kits One, two and three way kits are available, see sales literature.

Temperature catheter microprobes

Thermocouple probes

Thermocouple (type K), Ni/NiCr microwire in polyethylene tube, flexible

C8.B Thermocouple probe for complete bolt kits IMx.xx

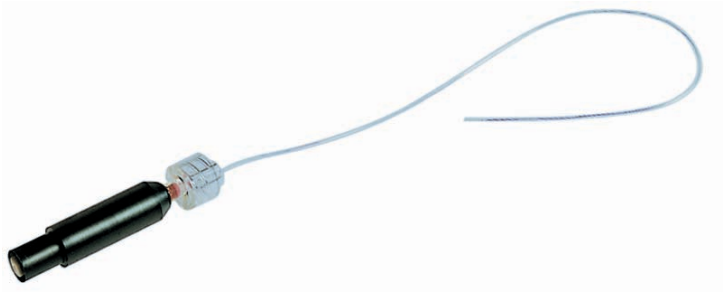

Fig. 7: C8.B temperature probe

Probe type	Length of the temperature sensitive area (mm)	Distance from tip to sensitive area (mm)	ø catheter near the tip (mm)	ø catheter near the root (mm)	Catheter length (mm)
C8.B	3	2	0.8	0.8	126

VK4/VM5 Kit for check of zero display

7 Explanation of the Symbols on the Packaging of Sensors and Accessories

The contents of the package is exclusively intended for single use (disposable).

The year and last date of the month (e.g. 2001-03) in which the product can be used are indicated next to this symbol. The content of the package can be used safely up to this date.

The lot number of the package contents is indicated next to this symbol.

This symbol identifies the serial number of the package contents. In oxygen probes, the serial number corresponds to the "probe number".

The year and month, (e.g. 2001-02), of manufacture of the package contents are indicated next to this symbol.

This symbol identifies the model number of the package contents.

The package contents have been sterilized with ethylene oxide gas.

The package contents have been sterilized by gamma irradiation.

Caution: Consult accompanying documents

This symbol shows the permissible storage temperature.

Federal (USA) Law restricts this device to sale by or on the order of a physician.

8 System Set Up

Assembly

The instrument must be switched off before connecting or disconnecting the LICOX bus connector (No. 10 of Fig. 9) or the low-voltage power supply connector (No. 7 of Fig. 9) .

Self-locking connectors are used on Licox cables; these connectors must not be turned. To release or to connect a cable, pull or push the connec tor without turning it. Hold the connector housing and never pull on the cable.

1. Connect the low voltage output cable of the LICOX power supply to the socket (No. 7 of Fig. 9) provided at the rear panel of the LICOX CMP instrument.

Only use the original LICOX power supply (REF:A10)! Use of an other power supply could endanger the patient's safety and could damage the LICOX instrument.

The connection voltage is marked on the base of the power supply (120 V AC).

2. Connect the blue $p_{bt}O_2$ probe cable (REF: BC10PA) to socket (No. 2 of Fig. 8) on front panel.

3. The potential equalisation plug (No. 12 of Fig. 9) at the rear panel of the instrument may be connected to the hospital ground system, if avail able.

Functional Check of the System

The proper assembly and functioning of the instrument and the $p_{bt}O_2$ probe cable can be checked using the test equipment delivered with them (REF: BC10R). The procedure for this is described in chapter 11.

The proper functioning of the system should be checked annually and whenever appropriate function is in doubt.

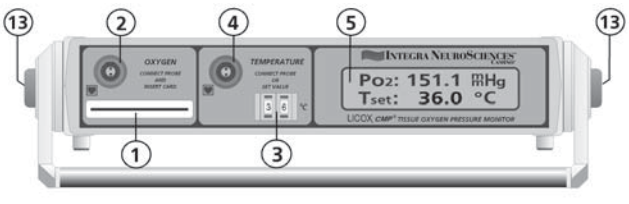

Fig. 8: Front Panel of the LICOX CMP Monitor

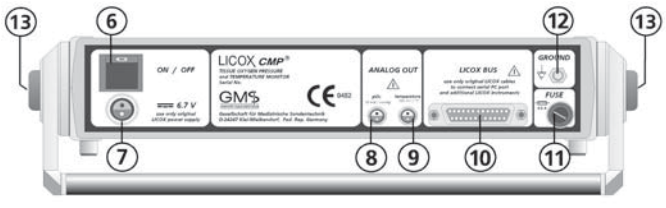

Fig. 9: Rear Panel of the LICOX CMP Monitor

Connecting the LICOX CMP to other Devices

☞ The analog signal outputs (No. 8 and No. 9 of Fig. 9) are provided for connection to the patient bedside monitors via the LICOX Monitor Link LML.1, D1. Please refer to the Monitor Link Directions for Use (DFU) for detailed instructions. Connect only to CF rated equipment.

9 Measuring $p_{bt}O_2$

Checks Prior to Monitoring

Functionality of the instrument (without probe) may be tested before use. (See Chapter 11.)

The function of the $p_{bt}O_2$ catheter may also be checked before use (see the section in this chapter entitled *Plausibility Check).*

Connecting the Probe
Starting the Measurement
Temperature Compensation

☞ Checking the probe:

Only use the probe if its sterile packaging is not open,damaged or broken.
Only use the probe before the expiration date labelled on the package.
Only use the probe if it has been stored correctly.

a Connect the blue probe cable (REF: BC10PA) to the $p_{bt}O_2$ probe input of the LICOX CMP instrument (No. 2 of Fig. 8) and connect the probe.

☞ Do not discard the probe packaging before the probe smart card has been removed.

b Switch on the LICOX CMP unit; the switch (No. 6 of Fig. 9) is at the rear panel of the device.

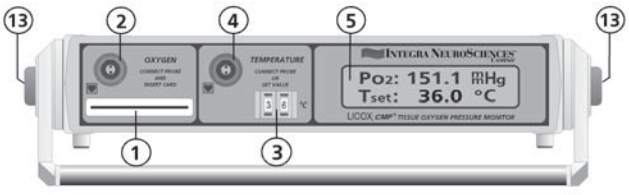

Fig. 8: Front Panel of the LICOX CMP Monitor

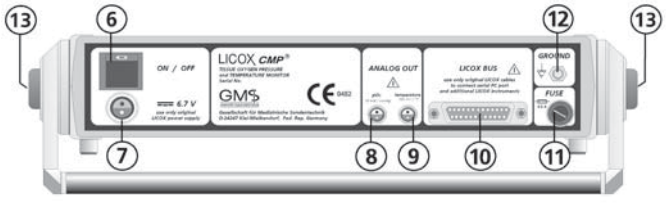

Fig. 9: Rear Panel of the LICOX CMP Monitor

c Insert the smart card into the card slot (No. 1 of Fig. 8) of the LICOX CMP instrument until it snaps into position. The metallic contact pads on the card face downwards. The arrow shows the direction of insertion. Probe calibration data are stored on the smart card.

d Temperature Compensation:

Alternative 1:
Input patient temperature via the code switch (No. 3 of Fig. 8) in °C ; the set temperature value then appears on the LCD display (No. 5 of Fig. 8) and is designated **T_{SET}**. The input temperature may be corrected during use.

☞ If the tissue temperature is set incorrectly, e.g. 1°C too high, then the $p_{bt}O_2$ value is underestimated by approx. 4% and vice versa.

Alternative 2:
A temperature catheter may be connected to the CMP monitor (no. 4 of Fig. 8). The temperature value measured in this manner will appear on the LCD display (No. 5 of Fig. 8) as **T_{mp}**. Connect temperature probe cable (REF BC10TA) to socket (No. 4 of Fig. 8) on front panel. Connect the green probe cable (REF BC10TA) to the C8.B temperature probe and the CMP monitor if temperature measurement is desired. Use only LICOX temperature probe C8.B with the LICOX CMP monitor.

☞ If the temperature is measured with a catheter, the $p_{bt}O_2$ value is only correctly compensated for temperature when the catheter tip is actually located in tissue.

After the probe has been implanted, the $p_{bt}O_2$ value to which the tip of the probe is exposed is displayed. The $p_{bt}O_2$ catheter may be disconnected from the CMP monitor and connected to another as long as the smart card is also transferred to the second CMP monitor.

The fluid-filled protector tube of the probe should not be discarded if the function of the probe is to be checked after the measurement.

☞ If the probe is continuously operated for more than 5 days then the measurement error can exceed the defined limits.

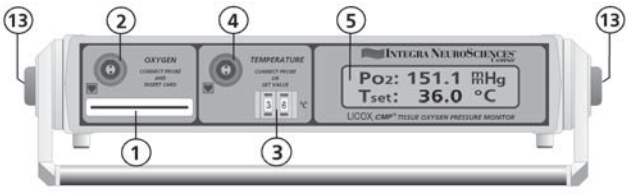

Fig. 8: Front Panel of the LICOX CMP Monitor

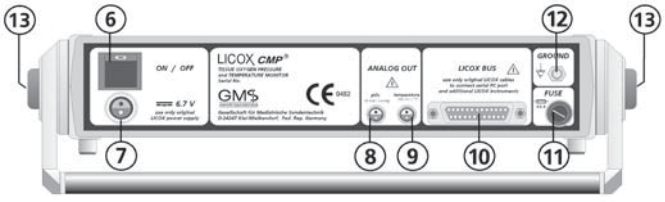

Fig. 9: Rear Panel of the LICOX CMP Monitor

Data Recording

A patient monitor may be used to display and record data. Connection of the LICOX system to patient monitors is described in Chapter 8.

Plausibility Check

Plausibility check of catheter sensitivity

The sensitivity of the probe can be determined before and after measurement. To perform a check after measurement, blood and tissue must be carefully cleaned from the probe (with a gauze pad soaked in water) and the probe must be re-inserted into its humid protection cap.

To check the probe, insert it with its protector tube and a temperature catheter (C8.B) into the test tube provided with the temperature catheter (a temperature controlled water bath can be used instead of the tube).

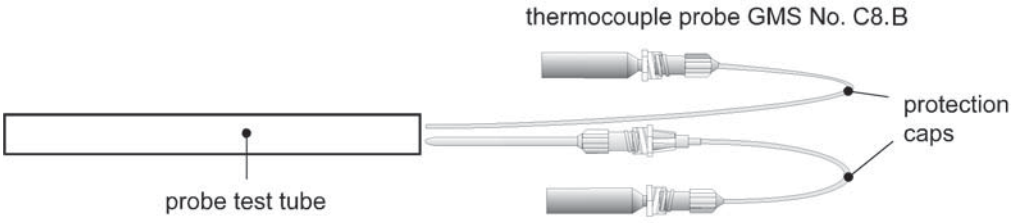

Fig. 10: Checking the probe sensitivity

Connect the oxygen probe to the blue probe cable (REF: BC10PA) and the temperature catheter to the green cable (REF: BC10TA). Turn on the instrument. After a run-in time of approximately 15 minutes, a $p_{bt}O_2$ value of approximately 150 mmHg should be displayed at sea level and normalized barometric pressure, respectively (altitude zero, 760 mmHg). The exact value expected for the display of $p_{bt}O_2$ in room air saturated 100% with water vapor (probe in its moist protector tube) depends on the temperature and the barometric pressure, i.e. the weather and the altitude of the test site above sea level.

The $p_{bt}O_2$ value in air varies by less than 5%, due to weather. The influence of temperature and barometric pressure on the $p_{bt}O_2$ value in air can be read from the following table, a 100% water vapor saturation and a reference air pressure of 760 mmHg at sea level is assumed.

$p_{bt}O_2$ of air saturated 100% with water vapor, calculated for various temperatures and barometric pressure values or altitudes above sea level, respectively; where the reference barometric air pressure is assumed to be 760 mmHg at sea level; $P_h = P_0 e^{-0.125 h}$ (P_h = barometric pressure at height, P_0 = barometric pressure at sea level, h = height in km)

		pO2 / mmHg at 100% humidity					
barometric pressure	altitude	22 °C	25 °C	28 °C	31 °C	34 °C	37 °C
760 mmHg	0 m	154	153	152	151	150	149
750 mmHg	100 m	152	151	151	149	148	147
741 mmHg	200 m	150	149	148	147	146	145
732 mmHg	300 m	148	148	147	145	144	143
723 mmHg	400 m	146	146	145	144	142	141
714 mmHg	500 m	145	144	143	142	140	139
705 mmHg	600 m	143	142	141	140	139	137
696 mmHg	700 m	141	140	139	138	137	135
688 mmHg	800 m	139	138	137	136	135	133
679 mmHg	900 m	137	136	135	134	133	131
671 mmHg	1000 m	136	135	134	133	131	130
630 mmHg	1500 m	127	126	125	124	123	121
592 mmHg	2000 m	119	118	117	116	115	113

Checking probe zero after removal from patient

Prior to the zero check, the probe must be carefully cleaned of blood and tissue. The probe zero displayed is checked in a zero oxygen solution (REF: VK4) that has been injected into a glass test tube. In the zero solution the expected $p_{bt}O_2$ display is 0 mmHg. The measured value of 0 mmHg will be displayed approximately 15 minutes after injection of the solution after contaminant oxygen is chemically bound in the zero solution. (The formula of the zero solution is: One liter deionized and nitrogen saturated water. 16.3 g Na_2SO_3 dissolved in water as oxygen absorbent together with 2.6 g $Na_2B_4O_7$ as accelerator.)

The zero solution is functional for a short period after breaking open the ampule:

- less than 15 min. in a syringe made of plastic material as oxygen is diffuses from the ambient air through its plastic wall
- approx. 3 h in a glass test tube

Sensor Implantation Technique

Please refer to Directions for Use (DFU) for Models CC1.SB and C8.B, listed in the DFUs for bolt kits IM1.S, IM2.S, IM3.ST, and IM1.T.

Troubleshooting

Problems due to instrument malfunction

- **Power failure**

  If the building power supply or the LICOX CMP low-voltage supply is interrupted, the device restarts automatically after the power supply has been re-established. The user does not need to restart the instrument or recalibrate.

- **Removal of the smart card during measurement**

  Measurements are interrupted when the smart card is removed. The message **please insert probe card** appears on the LCD display (No. 5 of Fig. 1). For the duration of this message, zero values of measured $p_{bt}O_2$ are transmitted by the analog serial outputs of the CMP monitor. Measurements will continue after the card is re-inserted.

- **Electrical disturbances**

  Strong electromagnetic disturbances can result in $p_{bt}O_2$ measurement errors. Errors can continue for a few seconds after the disturbance. These disturbances may occur when using a high-frequency scalpel or during cardioversion, e.g. during cauterization.

- **Damage to cable**

  If a probe cable (REF: BC10PA and BC10TA) or an extension cable (REF: BC10PV and BC10TV) is damaged, measured values can be incorrect or the measurement can be interrupted. The damaged cable must be replaced.

  Cables are sometimes damaged when the locking mechanism of the connector is not operated correctly (never rotate the connector housing; it may only be pulled or pushed). The cable will break if it is pulled with excessive force when the bayonet is locked.

  If concentrated alcohol is used for cleaning the cable and is applied for more than approx. 10 seconds, the silicone coating around the cable may be damaged. Moisture can then enter the cable.

- **Wet probe and cable connectors**

  The $p_{bt}O_2$ probe is not waterproof. Do not allow liquids to contact the connector. Do not dip into liquids.

- **Temperature gradient in the housing of the temperature probe connector**

  The temperature measurement may be inaccurate if the connector of the temperature probe is subjected to significant changes in temperature or if the temperature of

the connector is beyond the defined range of 18°C to 30°C. This may happen, for example, during rheumatological cryotherapy or due to direct exposure to strong sunlight. If the probe connector is held with a warm hand, the temperature measurement may be inaccurate until it is released.

- **Device defects**

  The LICOX CMP instrument displays error messages if it has an internal defect.

  Error no. 1 to *error no. 3* indicate that a computer component is defective.

  Error no. 4 points to a defect in the preamplifiers. If error message no. 4 continues to be displayed after both probe cables have been removed, then the preamplifier in the CMP monitor is defective. If *error no. 4* is displayed and the cables are attached to the monitor, then the probe cables are defective or the connector of the cable may be contaminated or wet. A short occurrence of *error no. 4* immediately after connecting a probe or when using a high frequency (HF) scalpel or an electrocautery device is normal.

  If the probe is touched by cautering forceps and is burned through, the preamplifier of the monitor can be damaged. The same applies when the probe is cut by an HF scalpel.

Fault in operation

- **Discarding the smart card or use of the wrong smart card**

  If the smart card is discarded with the probe packaging before use, the probe can not be used. If the wrong smart card is used with a probe, incorrect measurements result.

- **Using the probe longer than the recommended duration of use**

  If the probe is used continuously for more than 5 days the measurement error could exceed the defined range.

- **Bending the probe**

  In the tip zone (most distal 6 cm) of a probe, the radius of curvature must not be smaller than 2 mm. If the probe is bent on itself it is not destroyed but the measurement is interrupted.

- **Cutting and tearing**

  The catheters will no longer function if they are cut or torn.

Risks to the patient

- **General risk**s

  The LICOX Brain Oxygen Monitoring System is intended for use by a qualified physician. The physician should observe sterile technique and general surgical precautions when penetrating human tissue. Contraindications for needle insertion into the body also

apply, e.g. considerable coagulopathy and/or susceptibility to infections. A thrombocyte value of less than 50,000 per µl is a clear contraindication.

- **Special coagulation problems**

  In order to avoid hemorrhage in the area of implantation, blood coagulation must be carefully monitored when measuring in the brain during total body hypothermia, or in patients in hepatic coma or suffering from other diseases which could impair blood coagulation.

- **Risks of cerebral measurements**

  When using a bolt kit for intracranial measurement (e.g. REF: IM1), the following risks to the patient must be considered:

☞ If a drill-bit other than that delivered with the complete intracranial bolt kit is used, the hole may be too large or too small; the skull bolt will then either not fit correctly, get stuck half way when turning in a hole that is too small in diameter, or may even break if excessive force is applied.

Danger of confusing the drill-bits: The LICOX IM1 System is supplied with a drill-bit 3.8 mm in diameter; the ICP-bolt of Integra NeuroSciences, Camino Model 110-4B has a drillbit 2.7 mm in diameter. **Use the drill-bit supplied with the LICOX device.**

☞ Before drilling, the drill-stop must be correctly positioned on the bit taking into account the thickness of the skull. The tip of the drill-bit should penetrate the inner table by not more than 1 mm. Use a hand operated drill only. Do not use drills driven by compressed air.

☞ *If the dura mater is not incised (with a small cutting instrument) before the stylette is advanced, the dura mater could be pulled away from the skull, possibly resulting in hemorrhage.*

☞ The drill hole must not be made too near to the sagittal line, to avoid hitting the superior sagittal sinus, a parasinoidal sinus or the stem area of superior cerebral veins. Even taking this into account, a risk of hemorrhage remains.

Before drilling, always ensure that neurosurgical treatment and a CT scanner are available in case of severe bleeding at the twist drill hole.

☞ In general, there is a risk of infection due to use of intracranial catheter instruments. It is recommended that LICOX probes not be left in tissue for more than 5 days.

To avoid infection, the introducer must be sealed. If the seal is not made, cerebrospinal fluid may appear within the outer tube of the introducer. The seal should be tightened immediately if cerebrospinal fluid begins to enter the introducer tube.

Artifact

- **Movement artifact**

  Extreme acceleration of the probe tip (e.g. during continual knocking of the catheter tip on the edge of a table) results in an increased signal of usually not more than 15%.

- **Run-in drift**

  After implantation of a probe it takes 1 - 2 minutes before the local $p_{bt}O_2$ is correctly displayed. However, due to the microtrauma of implantation, the initial $p_{bt}O_2$ values displayed may not represent the $p_{bt}O_2$ of the surrounding tissue.

  After implantation, the run-in time (time until the $p_{bt}O_2$ values are representative of the surrounding region of the brain) may be as long as 2 hours.

- **Hemorrhage due to probe implantation**

  In rare cases, e.g. if a vessel is punctured during implantation or when coagulation is insufficient, hemorrhage can occur. The measured $p_{bt}O_2$ values are generally above the tissue values for the duration of bleeding. After the bleeding has stopped, the $p_{bt}O_2$ indicated is normally below it's value in surrounding non-affected tissue if the blood infiltration surrounding the puncture is thicker than approximately 100 µm.

- **Bypass for cerebrospinal fluid**

  If a patient has enlarged or shifted cerebral ventricles the probe or its introducer may puncture the lateral ventricle when inserted (the probe tip reaches approximately 35 mm below the dura level). If this occurs, the probe will create a channel that directly connects the inner ventricular system with the subarachnoid space, bypassing the natural pathways. Because of the pressure difference between the lateral ventricle and the subarachnoid space, it is possible that cerebrospinal fluid (CSF) from the ventricle could flow along the probe. The measured value then would correspond to the oxygen partial pressure of the CSF and is not representative of the surrounding tissue.

- **Displacement**

  The actual position of the sensor must be considered for interpretation of data. It is always possible that the sensor has displaced from the intended location.

- **Halothane Sensitivity**

  Halothane affects the measured values of polarographic $p_{bt}O_2$ probes; including the LICOX probe. Under the influence of halothane, the $p_{bt}O_2$ measurements are over-estimated. Other anesthetic gases such as nitrous oxide (N_2O), enflurane and isoflurane can be used without impairing the accuracy of the measurement.

10 Cleaning, Disinfection, Sterilization and Disposal

☞ Do not allow cleaning liquid to enter the smart card slot of the instrument or into connectors of the cables and/or the LICOX CMP instrument .

☞ The power supply will be destroyed if liquid enters into it's housing. Immediately discontinue use of this power supply even if it is apparently unaffected.

☞ Do not use a cable when its socket is damp, e.g. shortly after sterilization .

The Instrument

The LICOX CMP instrument may be cleaned with a towel that has been dampened with an aqueous soap solution which may also contain formaldehyde. Diluted alcohol-based disinfectant solutions may also be applied. Solvents containing phenol should not be used.

The Cables

Blood and tissue remains may be removed from the cables with a towel that has been dampened with an aqueous soap solution which may also contain formaldehyde. Disinfectants containing a high percentage of alcohol or phenol will damage the cables.

The extension cables (REF: BC10TV) for the temperature probe and for the oxygen probe (REF: BC10PV), can be sterilized in an autoclave (121°C, max. 3 bar, 20 min). Extension cables may not be sterilized by EtO or other methods.

The probe cables (REF: BC10PA and BC10TA), cannot be sterilized in an autoclave.

Cleaning contaminated cable sockets and connectors:

If salt solutions, blood or other body fluid enter the cable connectors or sockets, then the following cleaning procedure may be followed: The contaminated area of the connector may be rinsed with distilled water until all salty remains and blood contamination have been removed. A small brush can be used for this purpose (e.g. a large clean toothbrush). After blowing out the water, the connector (not the cable itself) may be immersed for approximately 5 seconds in ethanol (or isopropanol). Finally, the remaining alcohol must be blown out of the connector. The cleaning procedure may be repeated if required. After cleaning, the cable must dry for several hours.

Probes and Other Disposables

Probes and other disposables of the LICOX system are for single use only. This applies to all parts of the LICOX system whose model number begins with the letters C, V or I; this applies to the oxygen probe, (REF: CC1.SB) and the temperature probe (REF: C8.B) as well as the components of the complete bolt kit used for intracranial measurement IM1, etc.

Probes can not be resterilized.

Disposal of Probes and Disposable Accessories

Prior to disposal, any probe and other disposables which have been contaminated with blood, body fluid or tissue must be effectively disinfected.

The plastic parts of the disposable probes consist mainly of polyethylene or polyacetate.

None of the articles contain PVC.

Other synthetic materials (Telura/Novodur, polyimide, nylon, PTFE, silicone rubber) are only present in small amounts.

The packaging is made of paper, polypropylene, polycarbonate and polyethylene.

The metals used are steel, stainless spring steel, other stainless steels and copper as well as extremely small amounts of gold, silver and nickel in microwires and coatings.

Risks associated with disposal of LICOX CMP monitor, cable and accessories

The LICOX CMP device and accessories should be cleaned before disposal if contaminated with blood or tissue. The act of disposing of the LICOX CMP device and accessories poses no known risks. The LICOX CMP device and accessories may be returned to Integra Neuro Sciences for disposal if desired.

11 Maintenance

Provided that the hospital biomedical department has the equipment and knowledge to perform the instrument safety tests, the LICOX CMP instrument does not require periodical maintenance by the manufacturer.

The user should carry out the following checks at regular intervals as well as whenever there are doubts concerning the accurate function or the safety of the instrument.

Periodic Checks to be Carried Out by the User

Checking the pO_2 measurement:

Interval:
Once per year and as necessary

Checking the sensitivity of the CMP monitor:
Insert the test smart card #1 (part of the test set REF BC10R), into the card slot (No. 1 of Fig. 8). Connect the dummy-probe standard resistor (part of the test set REF BC10R) to the probe connector of the blue $p_{bt}O_2$ probe cable.

Disconnect any temperature probe from the green temperature probe cable. The temperature display must show the T_{SET} indicator. Set code switch (No. 3 of Fig. 8) to 22°C.

Expected values on the display: **pO_2 : 154.6mmHg**
T_{SET} : 22°C

If the instrument is working correctly, a $p_{bt}O_2$ value of 154.6 mmHg is now displayed on the LCD. If a value between 154.2 and 155.0 mmHg is displayed then the accuracy specifications of the unit are met. If values deviating from the aforementioned values are displayed, the instrument must be returned for re-calibration or repair.

Checking the zero pressure calibration of the CMP monitor:
After completing the previous test, disconnect the Dummy-Probe standard resistor from the blue $p_{bt}O_2$ probe cable. Leave the test smart card in its slot.

Expected values on the display: **pO_2 : 0.0 mmHg**
T_{SET} : 22°C

If the zero current is correctly adjusted a pO_2 value of 0.0 mmHg must be displayed on the LCD display. If any other value is displayed, the instrument must be returned for re-calibration or repair.

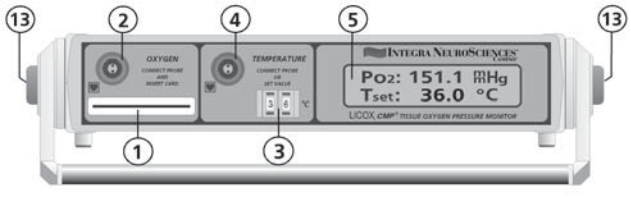

Fig. 8: Front Panel of the LICOX CMP Monitor

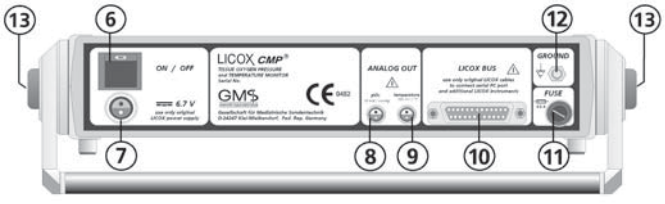

Fig. 9: Rear Panel of the LICOX CMP Monitor

Checking the temperature measurement

Interval:
Once per year and as necessary

Procedure:
Perform system set up as for a $p_{bt}O_2$ measurement using any probe smart card; the oxygen probe does not need to be connected for this test. Connect a temperature probe (REF C8.B); a temperature value labeled as T_{mp} will be displayed.

To test the temperature measurement, place the probe in a water bath inside a Dewar vessel with closed lid. Use at least two temperatures between 20°C and 45°C for the test. A calibrated precision thermometer with an absolute error below 0.05°C should be used as the reference instrument. Use at least 3 temperature probes, one for each of three separate tests.

Allow a warm up period of at least 30 minutes after the CMP monitor has been turned on and a temperature probe connected. Ensure that the probe connector is maintained at a temperature of between 18° and 30°C during the test. Ensure that the connector temperature remains constant for the duration of the test.

If the difference between the reference instrument display and the LICOX instrument display is less than 0.2°C, the LICOX CMP is working correctly within the limits of its defined accuracy. If different temperature values are displayed, the LICOX CMP instrument must be re-calibrated by the manufacturer.

Safety checks performed by the biomedical department of the hospital

The check includes the test of the maximum leakage current values according to IEC 601-1 CF (DIN EN 60601-1 CF).

Interval:
Once per year

Procedure:
Connect the test plug (REF BC10S) to the blue and green input sockets of the LICOX CMP device (No. 2 and No. 4 of Fig. 8) prior to the determination of the leakage currents. **If this test plug is not used then the input amplifiers could be destroyed!**
The measurements should yield the following results:

- device leakage current (IEC 601-1, subclause 19.4.f): < 10 µA
- patient leakage current (IEC 601-1, subclause 19.4.h): < 10 µA
- patient leakage current with main voltage on the F-type isolated applied part (IEC 601-1, subclause 19.4.h.2): < 10 µA

☞ Should the measured values exceed these limits the instrument must not be used. The instrument must be returned for repair.

The patient safety test must be concluded with a complete functional test to avoid any problems that might occur during the test procedure.

12 Technical Specifications

LICOX CMP Instrument

Instrument type:

• LICOX CMP

Principle:

• $p_{bt}O_2$ measurement: polarographic electrochemical sensor

• Temperature measurement: Type K thermocouple

• Displayed values update rate: once per second

Preamplifier:

• For $p_{bt}O_2$ probe: current amplifier, input 0 - 5000 nA, resolution 0.2 nA

• For temperature probe: voltage amplifier, input 0 - 4 mV, resolution 4 µV

Outputs:

LICOX CMP, type AC3 master instrument:

• Analog outputs: 0 -10 V, smallest increment 0.24 mV, 150 W impedance

• Connectors for both $p_{bt}O_2$ and temperature signals

• Resolution: 10 mV/mmHg for $p_{bt}O_2$ (10V = 1000 mmHg)

100 mV/°C for temperature signal (10V = 100 °C)

Display:

Alphanumeric LCD

• $p_{bt}O_2$: 0.0 - 1999 mmHg

• Temperature: 0.0 - 99.9 °C

• Text to explain operation and parameters used

Calibration:

Calibration data for the $p_{bt}O_2$ sensor is provided to the LICOX CMP instrument via a smart card. Temperature probes are tested/selected during manufacture by comparison to reference temperature values. The $p_{bt}O_2$ and temperature channels of the CMP monitor are calibrated during it's manufacture.

Accuracy in Long-term Operation:

Accuracy determined during continuous $p_{bt}O_2$ measurement at 37°C:

• $p_{bt}O_2$ 0–20mm Hg ± 2mmHg

• $p_{bt}O_2$ 20–50mm Hg ± 10%

• $p_{bt}O_2$ 50–150mm Hg ± 12%

• Temperature ± 0.2°C

• Duration of Use: 5 days maximum

• Duration of Use: 5 days maximum

Power supply / Power Consumption:

Use only original LICOX CMP power supply (REF:A10)

Power supply output: 7.5 VDC, 1.7 A

Building power supply output: 120 V AC, 50 - 60 Hz

Main Fuse:

500 mA, slow-blow-fuse

Protection against electrical shock:

Class II, Type CF applied parts: pO2 catheter, temperature catheter

Protection against harmful ingress of water:

ordinary

Degree of safety in the presence of flammable anesthetics mixture with air or with oxygen or nitrous oxide:

not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide

Mode of operation:

continuous

Operating Limits:

temperature:	+10 to 40°C
pressure:	700hPa to 1060 hPa
humidity:	30% to 75% RH non condensing

Shipping/storage Limits:

temperature:	0 to +50°C
pressure:	500hPa to 1060 hPa
humidity:	0% to 95% RH non condensing

Dimensions and Weight:

34 cm (breadth) x 32 cm (width) x 8.5 cm (height), 4200 g (net weight)

Language:

English

Appendix

Abbreviations

CPP	Cerebral Perfusion Pressure
CSF	Cerebrospinal Fluid
HP	Hewlett Packard
ICP	Intracranial Pressure
ICU	Intensive Care Unit
LCD	Liquid Crystal Display
OR	Operation Room
$p_{bt}O_2$	Brain Tissue Oxygen Partial Pressure

Terms of Sale

Pricing:

Prices stated in specific written quotations are firm for thirty days from the date given, and are otherwise subject to change without prior notice. Pricing terms stated on written agreements are governed by such agreements.

Minimum Order Requirements:

Minimum order requirement is $100 (a $10 handling charge will be added to any order under $100). For partial case orders, contact the Customer Service Department for quotation.

Shipments:

F.O.B. INTEGRA NEUROSCIENCES point of shipment within the continental United States. Shipping costs (including freight and insurance) shall be prepaid by INTEGRA NEUROSCIENCES and invoiced to Customers.

Ordering Procedure:

A written purchase order on Customer's form may be requested for purchases of INTEGRA NEUROSCIENCES products, but no terms set forth in a purchase order of Customer shall be binding on INTEGRA NEUROSCIENCES other than the terms that specify the product name, quantity and shipping.

Acceptance of Orders:

Orders are accepted upon approval by INTEGRA NEUROSCIENCES in Plainsboro, New Jersey.

Return Policy:

- Authorization number must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
- Non-sterile product must be returned in unused salable condition.
- Custom or special order products will not be accepted for credit.
- Credit will be issued subject to the following:

a) Goods returned prior to 3 months from ship date…20% restocking charge.

b) Goods returned between 3 and 6 months of ship date…50% restocking charge.

c) Goods will not be accepted for credit after 6 months.

Customer Service Department:

INTEGRA NEUROSCIENCES

311 Enterprise Drive

Plainsboro, New Jersey 08536

(800) 997-4868 (USA/Canada)

(800) 654-2873 (USA/Canada)

(609) 275-0500 (Outside USA)

(609) 275-5363 (FAX)

Integra NeuroSciences Limited Warranty

INTEGRA NEUROSCIENCES warrants that each new INTEGRA NEUROSCIENCES product is free from defects in material and workmanship under normal use and service for a period of two (2) years (except as otherwise expressly provided as to accessory items) from the date of delivery by INTEGRA NEUROSCIENCES to the first purchaser, but not beyond the “Expiration” date stated on any product labeling. Surgical instruments are guaranteed to be free from defects in material and workmanship when used normally for their intended purpose. Any covered product which is placed by INTEGRA NEUROSCIENCES under a lease, rental or installment purchase agreement and which requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement. If any such defect occurs during the warranty period or term of such placement agreement, the purchaser should communicate directly with the INTEGRA NEUROSCIENCES home office. If returned to INTEGRA NEUROSCIENCES at its home office, repair or replacement will be carried out at INTEGRA NEUROSCIENCES’s sole discretion, at INTEGRA NEUROSCIENCES’s expense, subject to the terms of this warranty and applicable agreements. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to INTEGRA NEUROSCIENCES shall be at CUSTOMER’s risk.

IN NO EVENT SHALL INTEGRA NEUROSCIENCES BE LIABLE FOR ANY LOSS OF USE, REVENUE OR PROFIT OR FOR ANY INCIDENTAL, EXEMPLARY, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES, WHETHER ARISING IN CONTRACT OR IN TORT, IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA NEUROSCIENCES PRODUCT. Further, this warranty shall not apply to, and INTEGRA NEUROSCIENCES shall not be responsible for, any loss or damages arising in connection with the purchase or use of any INTEGRA NEUROSCIENCES product which has been repaired by anyone other than an authorized INTEGRA NEUROSCIENCES service representative or which has been repaired or serviced using materials or parts provided, modified or designed by anyone other than INTEGRA NEUROSCIENCES or its authorized representatives, or which has been, altered in any way so as, in INTEGRA NEUROSCIENCES ’s judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been subject to improper or negligent installation or storage, or which has been subject to improper cleaning, sterilization or maintenance, or which has been subject to accidental damage arising from acts of God, electrical power damage, equipment malfunction, unusual stress, unreasonable operating procedures or abnormal or extreme operating conditions, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA NEUROSCIENCES.

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LICOX CMP Manual USA
Revision 03_US / 01_2004
2004-05-01
LICOX CMP Manual 03_US 1_2004.pmd
45136 Rev. C